(54) Title: CARDIOPULMONARY MONITORING SYSTEM WITH INTEGRATED BLOOD OXYGENATION SIGNAL QUALITY INDICATOR

(57) Abstract

A cardiopulmonary monitoring system (100) transmits and receives optical signals to and from the interior of a blood vessel via a fiberoptic catheter (10). The signals may be processed to obtain a measurement of the blood oxygenation saturation level of the blood within the blood vessel. The cardiopulmonary monitoring system includes a detector which detects optical signals. A detector (402) provides an electrical output signal which has an amplitude that is proportional to the intensity of the detected optical signal transmitted from the blood vessel. The monitoring system (100) further comprises a signal processing device (420), which includes means for comparing the amplitude of the output signal with a threshold amplitude value, monitoring the frequency with which the output signal exceeds the threshold value during a selected interval of time, and generating a first signal quality indicator value based upon the monitored frequency. The monitoring device (100) also monitors the magnitude variations in the output signal due to pulsatile blood flow through the blood vessel and generates a second quality indicator value in response thereto. The monitoring device (100) also monitors the amplitude of the output signal and generates a third signal quality indicator value in response thereto. The three indicator values are then compared, and the highest one is selected to be output as a quality display value. The output quality display value is indicative of the reliability of the blood oxygenation saturation level reading output by the monitoring system.

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CARDIOPULMONARY MONITORING SYSTEM WITH
INTEGRATED BLOOD OXYGENATION SIGNAL QUALITY INDICATOR

Field of the Invention

5   The present invention is related to fiberoptic cardiac
catheters.

Background of the Invention

Fiberoptic cardiac catheters are well known in devices
which measure the oxygenation of the blood between the
10   heart and the lungs. Typically, light in two or three
distinct wavelengths is introduced into the bloodstream by
means of transmitting fiberoptic lines. The light signals,
(generally in the red and infrared color bands), are
reflected and refracted by the blood so that a portion of
15   the light signals are received by sensing fiberoptic lines
which are also within the cardiac catheter. The
oxygenation of the blood may then be determined from the
information obtained from the received signals.

In simplified terms, the oxygenation of the blood is
20   measured by determining the color of the blood using the
fiberoptic catheter. As described in U.S. Patent Nos.
4,641,658 and 4,651,741, the oxygenation of the blood may
be determined using the information obtained from the
backscattering of red (R) and infrared (IR) signals.
25   Because the amplitude of both the R signal and the IR
signal is affected by, among other things, artifacts such
as clots and flow patterns, the oxygenation of the blood
has traditionally been measured by generating an R/IR
signal in which the artifacts cancel out. The oxygenation
30   percentage is a known function of the R/IR ratio, and the
oxygenation percentage can thus be measured. U.S. Patent
Nos. 4,641,658 and 4,651,741 are herein incorporated by
reference.

As the blood under test flows about the catheter tip,
35   the amplitude of the backscattered radiation (most notably

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the IR radiation) fluctuates as an AC signal in
synchronization with the patient's heartbeat.   It is
believed that this is due, in part, to the turbulence
created by eddy currents about the catheter tip as blood
5   flows past the catheter.   Generally, turbulent blood
scatters more light than stationary blood, so that, as the
blood alternately flows and rests with the heart's pumping
action, the amplitude of the received IR signal varies
accordingly.   The pulsatile fluctuations of the IR signal
10   typically exhibit sinusoidal characteristics and are
generally smooth with gradual changes in amplitude.   In
many instances, however, the amplitude of the received IR
signal exhibits spiking characteristics wherein a sharp
increase in amplitude occurs at each heartbeat.   This is
15   often the case when the catheter tip is positioned near the
wall of a blood vessel.   When the tip of the catheter
impacts or closely approaches the wall of a blood vessel,
the increased reflectivity of the vessel wall in comparison
with the blood itself causes a greater amount of light to
20   be reflected into the receiving fiberoptic line, thereby
causing the amplitude of the received signal to sharply
increase.   Since the vessel wall exhibits reflective
characteristics which are not necessarily related to blood
oxygen saturation, these substantial fluctuations resulting
25   in greatest part from the reflectance of the vessel wall
can introduce inaccuracies into the measurement of blood
oxygen.
    Various techniques have been used for reducing or
eliminating these substantial fluctuations.   In one system,
30   the catheter tip is enclosed in a cage-type structure to
prevent the tip of the catheter from impacting the vessel
wall.   While the cage structure may effectively separate
the catheter tip from the vessel wall, the structure also
greatly increases the tendency for deposits to form on the
35   catheter tip, an undesirable result.   In another system, a
signal filter removes data above a predetermined threshold

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amplitude in an attempt to eliminate any erroneous data. This approach may be effective as long as the artifact is not too severe, or does not last too long. However, if a large portion of the signal readings have to be filtered, 5   there may not be enough good readings to maintain tracking of oxygenation saturation levels.

Some techniques include displaying the IR signal intensity, which requires the user to interpret the display as to whether or not it is normal, and separate on/off 10 alerts for each condition detected. The user, however, has no direct interest in the particular characteristics of the signals that are detected. Instead, the user is concerned with whether or not the blood oxygenation reading is reliable.

15   Summary of the Invention
The present invention is a cardiopulmonary monitoring system which is connected to a fiberoptic cardiac catheter. The system transmits and receives optical signals to and from the interior of a blood vessel via the fiberoptic 20 catheter. The cardiopulmonary monitoring system comprises a detector for detecting an optical signal transmitted from the blood vessel and for generating an output signal in response thereto. The monitoring system further comprises a signal processing device. The signal processing device 25 includes a first signal processing means for comparing the amplitude of the output signal with a threshold amplitude value, monitoring the frequency with which the output signal exceeds the threshold value during a selected interval of time, and generating a first indicator based 30 upon the monitored frequency.

In a preferred embodiment, the system includes second and third processing means for generating second and third indicators respectively. The system further includes means for sensing the first, second and third indicators and 35 generating a quality display signal in response thereto. In a particularly preferred embodiment, the second

processing means monitors the magnitude variations in the output signal due to pulsatile blood flow through the blood vessel, and the third processing means monitors the amplitude of the output signal.

Another aspect of the present invention encompasses a cardiopulmonary monitoring system which comprises a detector for detecting an optical signal transmitted from the blood vessel and generating an output signal having a waveform in response to the optical signal. The monitoring system comprises a means for recursively generating a variable indicative a waveform characteristic, such as spikes in the waveform, and a means for generating an indicator based upon the variable.

The present invention further encompasses a method for monitoring an optical signal from a cardiopulmonary catheter comprising the steps of: 1) detecting the optical signal and generating a waveform in response thereto, 2) monitoring the spikes in the waveform during a second interval, and 3) utilizing the results of steps 1) and 2) to generate an indicator.

Brief Description of the Drawings

Figure 1 is a plan view of a fiberoptic cardiac catheter used in accordance with the present invention.

Figure 2 is a cross-sectional view of a section of tube of the catheter shown in figure 1.

Figure 3 is a front view of the cardiopulmonary monitoring apparatus of the present invention which shows the details of the display panel.

Figure 4 is a simplified block diagram which shows the processing circuitry used within the cardiopulmonary monitoring system shown in Figure 3.

Figure 5 is a flowchart which shows the overall method of processing cardiopulmonary data in accordance with the present invention.

Figure 6 is a flowchart which details the method used in accordance with the data acquisition and filtering

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subroutine block of Figure 5.

Figure 7 is a flowchart which details the method used in accordance with the update quality display signal subroutine block of Figure 5.

5   Detailed description of the Preferred Embodiment

Figures 1 and 2 show a side view and a cross-sectional view respectively of a fiberoptic cardiac catheter 10 which may be used in accordance with the present invention. The catheter 10 includes an elongated catheter tube 14 having
10   an inflation lumen 16, a distal lumen 18, a thermistor wires lumen 20, an injectate lumen 22, an RV port infusion lumen 24, and a fiberoptic lumen 26. A distal lumen tube 30, having a distal lumen hub 32 attached thereto, is fused to the tube 14 within the distal lumen 18. In a like
15   manner, an inflation lumen tube 34 with an inflation valve 36, an injectate lumen tube 38 with an injectate hub 40, and an RV port infusion tube 42 with an RV port infusion connector 44, are all fused to the tube 14 within the inflation lumen 16, the injectate lumen 22, and the RV port
20   infusion lumen 24 respectively. Thermistor wires (not shown) within a thermistor tube 48 having a thermistor connector 50 attached thereto, extend through the tube 14 within the thermistor wires lumen 20. Fiberoptic lines extend from a fiberoptic oximetry connector 55 within a
25   tube 57. The tube 57 is also fused to the catheter tube 14 so that the fiberoptic lines extend along the length of the catheter tube 14 within the fiberoptic lumen 26.

The catheter tube 14 may be extruded from a suitable biocompatible plastic material. The tube 14 is
30   advantageously flexible and sized to be received within a blood vessel. The tube 14 has a proximal end situated within a flexible jacket 60, and a distal end 62 to which a balloon 65 is connected. The inflation lumen 16 terminates within the balloon 65 so that the balloon 65 may be
35   inflated using the inflation lumen 16. In one preferred embodiment, the catheter 10 is a Swan-Ganz ® oximetry

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catheter, model 93A-780H-7.5F.

The fiberoptic lines within the lumen 26 may be single or multi-mode fiberoptic cables and are advantageously constructed to transmit light in the red and infrared frequency spectrum. At the distal end of the tube 14, the fiberoptic lines are exposed so that light may be radiated into, and received from, the bloodstream when the catheter 10 is inserted into a blood vessel. At the opposite end, the fiberoptic lines are optically connected to the fiberoptic oximetry connector 55. The connector 55 may be hooked up to a monitoring device 100 (Fig. 3).

The monitoring device 100 is capable of generating optical signals in the appropriate wavelengths (e.g., 660nm and 810nm) for transmitting along the fiberoptic lines. The monitoring device 100 is also capable of receiving and processing optical signals, so that the backscattered optical signals sensed by the receiving fiberoptic lines may be monitored and measured by the device 100. The monitoring device 100 advantageously includes an output display for presenting significant information to a user. Such information may include a blood oxygenation saturation reading in numerical 105 and graphical form 107, an alarm signal 110 to indicate conditions which may be dangerous for a patient, and a quality display signal 120, which indicates the reliability of the current blood oxygenation reading.

Figure 4 is a simplified block diagram which shows the general circuitry 400 used within the device 100 to process the incoming optical signals, and to output information to the display of the monitoring device 100. The circuitry 400 includes an electro-optical coupler 402 for receiving optical R and IR signals, and outputting corresponding analog electrical signals which have an amplitude that is proportional to the amplitude of the optical signals. The analog electrical signals are then transmitted to a gate array 410, which provides all required timing and control

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signals to the analog circuitry, and serves to convert the
analog signals to digital signals at a rate of one sample
per millisecond. The gate array 410 may pass the data in
either a data mode or an offset mode. The gate array 410
5   is set in the offset mode when it is desired to calculate
offset values, used to correct for system offsets, at each
gain level. During normal operation of the monitoring
system 100, the gate array 410 is set to the data mode, and
basically acts as an A/D convertor which averages 50 input
10 data samples at a rate of one sample per millisecond and
outputs a two-byte digital value every 50 ms. These
digital signals are then transmitted to a microprocessor
420. The microprocessor 420 performs most of the signal
processing and calculates output values which are sent to a
15 display driver 430, which in turn drives a display output
435. The microprocessor 420 also has access to a read only
memory (ROM) 450 and a random access memory 455.

Figure 5 is a flowchart which shows the overall method
of processing the data obtained from the light
20 backscattered from blood within a blood vessel. The method
begins in a block 500 and control is transferred to an
activity block 510, wherein the monitoring system 100 is
initialized and self tests are performed. Such tests
include power-up, offset determination of the R and IR
25 signals at each gain level, initiation of a watchdog-timer,
and initiation of run-time diagnostics. Once the
monitoring system has been initialized and the watchdog-
timer and run-time diagnostics are running, control passes
to a subroutine block 520, wherein the data from the
30 receiving fiberoptic line is acquired and filtered.

Basically, within the subroutine block 520, the
optical data is converted into electrical signals by the
optical coupler 402. These signals are then converted into
digital signals via the gate array 410. The gate array 410
35 then outputs these signals to the microprocessor 420
wherein the digitized signals are filtered and averaged.

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Initially, a baseline value and a threshold value are calculated, and those digital signals which are in excess of the calculated threshold value are clipped, so that they are equal to the threshold value. That is, the values which exceed the threshold value are assigned the value of the threshold, while those values which are not in excess of the threshold value remain unchanged. These values are then transmitted to a series of filters and averagers to provide values appropriate for calculating the blood oxygenation saturation level, as well as the blood flow rate. The subroutine block 520 will be described in greater detail in reference to Figure 6 below.

Once the data has been acquired and filtered in the subroutine block 520, control passes to an activity block 530, wherein the cardiopulmonary monitoring system 100 is calibrated and updated. The monitoring system 100 may be calibrated in two ways: in vitro, or in vivo. This calibration and update technique is described in detail in U.S. Patent No.4,651,741. Once calibration has occurred in the activity block 530, control passes to an activity block 540.

In the activity block 540, the value of the blood oxygenation saturation level is calculated and displayed. The blood oxygenation saturation level, S, may be calculated as:

$$S = AX^2 - BX + C - D/X \qquad (1)$$

where A, B, C, and D are constants determined by the design of the catheter 10, and X is calculated as:

$$X = (IROUT/REDOUT)*M - Z \qquad (2)$$

where M and Z are constants determined at calibration, and R and IR are the amplitudes of the filtered red and infrared digital signals respectively. The value of the

blood oxygenation saturation level, S, is then output to
the numerical display 105 and the graphical display 107
(Fig. 3).

Once the value of the blood oxygenation saturation
level has been out put to the displays 105, 107, control
passes to an activity block 550, wherein any alarm
conditions are checked. Such alarm conditions include a
high/low saturation alarm, a saturation "out-of-range"
alert, and a light "out-of-range" alert. The high/low
saturation alarm indicates that the blood oxygenation
saturation level of the patient has exceeded or dipped
below certain operator determined safety levels. The
saturation "out-of-range" alert is activated when the value
of X is above or below certain predetermined values (e.g.,
0.54 and 2.57 in one embodiment). Finally, the light
"out-of-range" alert is activated when the R or IR signal
is either overscale, or too small to depend upon an
adequate signal-to-noise ratio. For example, overscale may
occur when the amplitude of one of the received light
signals needs to be brought down to a lower gain, but the
gain scale is already on the lowest level. The low-light
alert is activated when the mean digital value of either
the R or IR signals over a period of two seconds is below a
certain digital value, and the gain scale is set to the
highest level. If any of the alarm conditions has been
activated, a flag is set to indicate which alarm has been
activated. Control then passes to a decision block 555
wherein a test is performed to determine if any of the
alarms have been activated. If so, then control passes to
an activity block 560, wherein the appropriate alarm
display is activated, and control is then passed to a
subroutine block 570.

If no alarms have been activated, then control passes
directly from the decision block 555 to the subroutine
block 570, wherein a quality display signal is updated.
The quality display signal indicates the reliability of the

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blood oxygenation saturation level readings output by the monitoring system 100. In a preferred embodiment, the quality display signal assumes values from one to four, wherein each value is indicative of the quality of the
5   saturation reading. A quality display signal value of "1" indicates that the blood oxygenation saturation level readings are normal, and have an accuracy of +/- 2%. A value of "2" indicates that the saturation readings are moderately degraded, and that the user may wish to adjust
10   the catheter 10 or monitoring system 100 to obtain more accurate readings. A value of "3" indicates that the saturation readings are significantly degraded and the probability of significant errors is increasing. At a value of "3" corrective action is suggested. A value of
15   "4" indicates that the saturation readings are very significantly degraded, and should not be relied upon. When the quality display signal is at level "4," corrective action is strongly recommended. The quality display signal is produced by selecting the highest of three indicator
20   values, wherein each indicator value assumes a value of one to four. In one embodiment, these three indicators are functions of 1) the frequency of clipping exhibited by the R and IR signals, 2) the calculated rate of blood flow in the host vessel, and 3) the shift in intensity of the IR
25   signal over successive half second intervals. The method of updating the quality display signal is described in detail with reference to Figure 7 below. Once the quality display signal is updated in the subroutine block 570, control returns to the activity block 540, wherein the
30   blood oxygenation saturation level is again calculated. This process is repeated continuously to provide suitable monitoring of the blood oxygenation saturation level while the catheter 10 is in place within a patient.

        Figure 6 is a flowchart which details the method of
35   acquiring and filtering data within the subroutine block 520. Due to the size of the flowchart, a first portion of

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the flowchart is shown on a drawing sheet labeled 6A, and a
second portion of the flowchart is shown on a drawing sheet
labeled 6B. The method begins in a begin block 600 and
control passes to a decision block 602 wherein a test is
5   performed to determine if the gate array 410 is in the
offset mode. If the gate array is in the offset mode,
control passes to an activity block 604 wherein the offset
values of the R and IR signals are calculated at each gain
range. This is advantageously done by reading in 500
10   successive input bits and calculating the offset value as:

$$OFFSET = INT(51200*(N1-1)/(499-N0)) \qquad (3)$$

where N1 is the number of digital 1's within the 500 bit
15   sample, and N0 is the number of leading and trailing zero's
(the number of zero's before the first 1 and after the last
1). The calculated offset value for the R signal is
designated as OSRED, while the calculated offset value for
the IR signal is designated as OSIR. In a preferred
20   embodiment, an automatic gain control AGC having gain level
values of 1, 4, 16, and 64 is employed which adjusts the
system gain as a function of the light intensities of the R
and IR signals. Thus, an offset value is calculated as
described above for each gain level. Control then passes
25   to an activity block 606 wherein the offset values for each
gain level are stored in the RAM 450. Control then returns
to the decision block 602. Once the gate array is no
longer in the offset mode, control passes to an activity
block 610 thereby indicating that the gate array 410 is in
30   the data mode.

        In the block 610, two-byte integer values
(representative of the R and IR signal intensities)
obtained from the gate array 410 at each 50 ms interval are
multiplied by a gain value of 64. The full scale value
35   (that is the maximum allowable value) of the integer values
is 800 so that, after multiplication, the new full scale

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value is 51200.   These new upscaled integer values are assigned to the variables RED and IRED. Once the new integer values representing the R and IR signal intensities are determined, control passes to an activity block 612.

5   In the activity block 612, initial maximum threshold values are set for both the R and IR signal values. These threshold values are used within a clipping subroutine, generally designated as a clipper 611, and are updated periodically.   In the clipper 611, the digital values

10   representing the intensities of the R and IR signals are filtered so that those values which fall above the maximum threshold value are assigned the same value as the threshold while those values that are not in excess of the threshold value remain unchanged. At the same time, the

15   values of the thresholds are periodically adjusted in response to the average amplitude of the R and IR signals. Once the initial values are set within the activity block 612, control passes to an activity block 614, wherein the most recent limit values for the R and IR signals are

20   calculated respectively as:

$$LIMRNEW = AVE2R + INT(REDOUT*3/8) \qquad (4)$$

$$LIMINEW = AVE2IR + INT(IROUT*3/8) \qquad (5)$$

25
where the values of AVE2R and AVE2IR, and REDOUT and IROUT are feedback values from the output of the processing routine. Control then passes to an activity block 616, wherein a limiting value LIMMIN is calculated for each of

30   the R and IR signals as a value, LORLOW, times 11/16. The value LOWROW is the light out-of-range value (the value which indicates that the R or IR signal intensity is too low for a given gain level) which may be determined in accordance with system requirements. However, if the gain

35   scale (i.e., 1, 4, 16, or 64) is at 64, then the value of LIMMIN is calculated as LORLOW*11/8. Once the limiting

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value LIMMIN has been calculated, control passes to a
decision block 618, wherein a test is performed to
determine if the value of LIMRNEW is less than the limit
value LIMMIN. If so, control passes to an activity block

5   620, wherein the value of LIMRNEW is set to the value of
LIMMIN and control then passes to a decision block 622. If
the value of LIMRNEW is not less than the value of LIMMIN,
then control passes directly to the decision block 622,
wherein a test is performed to determine if the value of

10   LIMINEW is less than the value of LIMMIN. If so, control
passes to an activity block 624, wherein the value of
LIMINEW is set to the value of LIMMIN, and control then
passes to a decision block 626. If the value of LIMINEW is
not less than the value of LIMMIN, then control passes

15   directly to the decision block 626, wherein a test is
performed to determine if the number of clipped values (NC)
over the last 500 ms update period (the time necessary to
average ten signal values each of the R and IR signals) is
equal to 0 or 20 (the minimum or maximum values which NC

20   may assume).

        If the value of NC is not equal to 0 or 20, then
control passes to an activity block 628, wherein the new
threshold values for the R and IR signals are calculated
as:

25

$$LIMRED = INT[(3*LIMRED + LIMRNEW)/4] \qquad (6)$$

$$LIMIR = INT[(3*LIMIR + LIMINEW)/4] \qquad (7)$$

30   so that, in essence, a weighted average is calculated to
determine the new threshold as a function of the old
threshold value and the most recent limit value. If the
value of NC is equal to zero or 20, this indicates that the
old threshold values should be radically altered, and

35   control passes instead to an activity block 630, wherein
the new R and IR threshold values are directly assigned the

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values of LIMRNEW and LIMINEW respectively. This initialization of the values of LIMRNEW and LIMINEW serves to decrease settling time so that the calculated limits do not take a long time to reach their appropriate values
5   when the monitoring system is first turned on.

Once the new threshold values have been determined, a fresh sample of 20 signal values (10 R and 10 IR) are filtered. To accomplish this, control passes to a decision block 634 wherein a test is performed to determine if the
10 digital value corresponding to the signal intensity of the R signal, RED, is greater than the newly determined threshold LIMRED. If so, then the output of the R clipper, which shall be designated as the variable E2RED, is assigned the value of the threshold, LIMRED, and NC is
15 incremented by one in the activity block 636. If the value of RED is not greater than the threshold LIMRED, then the output E2RED of the R clipper retains the value of the input, (i.e., E2RED = RED). In a similar manner, the digital value representing the input IR signal is clipped.
20 Control passes to a decision block 642, wherein a test is performed to determine if the value of IRED is greater than the value of the threshold LIMIR. If so, then control passes to an activity block 646, wherein the output of the IR clipper, E2IR is assigned the value of the threshold
25 LIMIR, and the value of NC is incremented by one. If the value of IRED is not greater than the value of LIMIR, then control passes instead to an activity block 644, where E2IR is assigned the value of the input, IRED. Thus, each of the digital values input to the clipper 611 retains its
30 original value or is assigned a new value that is equal to the threshold value.

Once the values have been clipped, control passes from either block 644 or 646 to an activity block 650, wherein the digital values output from the clipper are
35 filtered and averaged. The general procedure followed within the filtering and averaging activity blocks may be

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described in program form as follows:

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DO;
      SUM = 0;
      DO  I = 1 TO N;
            G = G -F + E;
            F = INT(G/K);
            SUM = SUM + F;
            END;
      AVE = INT(SUM/N);
      END;
```

where N represents the number of values being averaged, E
is the input variable, G is an intermediate filtering
variable, K is a filtering constant, F is the filter output
value, and AVE is the average value output.   In the
filtering and averaging activity block 650, the number of
samples being averaged is 10 (N = 10) and the value of the
filtering constant K is 32.   Thus, assuming an input value
every 50 ms, an F value is output every 50 ms, an AVE value
is output every 500 ms (10 * 50 ms), and the filter time
constant is 1.6 seconds (32 * 50 ms).   Note that during in
vitro calibration, the time constant is usually smaller
(e.g., 400 ms corresponding to K = 8).   Therefore, within
the activity block 650, an F2 value is output every 50 ms,
and an AVE2 value is output every 500 ms for both the R and
IR signals.

Once the signals are averaged and filtered in the
block 650, control passes to an activity block 654, wherein
final output values of the R and IR signals are calculated
by subtracting previously determined offset values, OSRED
and OSIR, as follows:

$$REDOUT = AVE2R - OSRED \qquad (8)$$

$$IROUT = AVE2IR - OSIR \qquad (9)$$

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Note that the values AVE2R, AVE2IR, REDOUT, and IROUT are fed back to the clipper so that they may be used to calculate the new limit values, LIMRNEW and LIMINEW, which are used to adjust the threshold levels. The values of REDOUT and IROUT are also used to calculate the blood oxygenation saturation level within the activity block 540 of Figure 5. Once REDOUT and IROUT are calculated within the activity block 654, control then passes to an activity block 658, wherein the values of REDOUT and IROUT are stored within the RAM memory 450.

Control then passes to an activity block 662, wherein a difference signal, E3IR, is generated by subtracting the filtered IR value, F2IR, from the value, E2IR, output from the IR clipper, and taking the absolute value (i.e., E3IR = ABS(E2IR - F2IR)). This difference signal may be used to calculate a cardiac flow monitor value, CFM, that is indicative of the rate of blood flow past the catheter 10 within a blood vessel. Note that only the IR signal is used to indicate the rate of blood flow past the catheter. Once the difference signal E3IR is calculated, control passes to an activity block 668, wherein the signal E3IR, which is produced every 50 ms, is filtered and averaged according to a similar method described in accordance with the activity block 650 (i.e., K=32, and N=10). Thus, an F3 value is generated every 50 ms, and an AVE3 value is generated every 500 ms. Control then passes to an activity block 672, wherein an index value E4 is calculated as AVE3/IROUT every 500 ms. The signal E4 is then filtered and averaged within an activity block 676.

The filtering done in the activity block 676 is slightly different than the filtering described in accordance with the activity block 650. In particular, the values of N and K are 4 and 16 respectively. Also, since the incoming data (i.e., E4) is fractional, the program steps:

$$G = G - F + E; \qquad (10)$$
$$F = INT(G/K); \qquad (11)$$

5   in the filtering program described above are replaced with a single step:

$$F4 = F4 + (E4 - F4)/K \qquad (12)$$

10   to allow for fractional values at the output. The value of AVE4 which is calculated every 2 seconds is then assigned as the CFM value within an activity block 680. Control then passes out of the subroutine block 520 and proceeds to the calibration and update block 530 as shown in Figure 5.

15   Figure 7 is a flowchart which details the method used in accordance with the update quality display signal s..broutine 570 of Figure 5. The method initiates in a begin block 700 and proceeds to an activity block 710, wherein the intensity shift (IS) signal quality indicator

20   value is determined. This value is determined as a function of a baseline level as will be discussed below. Once the IS quality indicator is determined in the activity block 710, control passes to an activity block 720, wherein the cardiac flow monitor (CFM) indicator value is

25   determined. This value is a function of the CFM index value, AVE4. Control then passes to an activity block 730, wherein a clipping frequency indicator (CFI) value is determined as a function of the last indicator value as well as the number of clips NC within the last 500 ms

30   update cycle. Control then passes to an activity block 740, wherein the highest indicator value of the three indicators (i.e., IS, CFM, and CFI) is selected as the quality display signal. This signal 120 is displayed as a bar graph on the display panel of the monitoring apparatus

35   100 shown in Figure 3. Recall that each of the three indicators assumes a value of 1 to 4, so that the range of

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values of the quality display signal is also 1 to 4. Control then returns to the activity block 710, and the cycle repeats. Note that each indicator value is determined at 2 second update cycles so that the quality display signal is also updated every 2 seconds. A detailed account of the procedure for determining the indicator values for the IS, CFM, and CFI signals follows.

Intensity Shift:

The IS value is based upon the IROUT signal relative to a baseline value. The baseline value is obtained or updated at each calibration or hematocrit update. To obtain the baseline value, a period of approximately 12 seconds is allowed to pass after the monitoring system initiates operation. Following this delay period, the next 16 values (corresponding to 8 seconds) of AVE2IR are averaged. This eight second average is then normalized by multiplying by 64, and dividing by the present gain level to determine the baseline value. Note that the monitoring system includes an automatic gain control (AGC) system to retain accuracy over an extended range of light intensities transmitted by the fiber optic cardiac catheter 10. In a preferred embodiment the four gain levels are 1, 4, 16, and 64. Thus, if the eight second average is determined to be a digital value of 12608, and the monitoring system is presently operating at a gain level of 16, the baseline value would be calculated as (64*12608/16) or 50432.

Large variations from this calculated baseline are indicative of large intensity shifts in the IR signal which may be due to kinks in the fiberoptic lines within the catheter 10, so that the level of the SI indicator increases as the IROUT signal increases in variation relative to the calculated baseline value. In particular, the IS level is determined from the percent change from the baseline and the following limits:

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```
LEVEL 1:              0.67 < IROUT/BASE < 1.50
LEVEL 2: 0.5< IROUT/BASE <0.67, OR 1.5< IROUT/BASE <2.0
LEVEL 3: 0.4< IROUT/BASE <0.50, OR 2.0< IROUT/BASE <2.5
LEVEL 4:              IROUT/BASE < 0.40, OR  2.50 < IROUT/BASE
```

Thus, if the value of the ratio IROUT/BASE is 0.45, then an IS indicator value of 3 will be generated.

Cardiac Flow Monitor:

The calculation of the CFM index, AVE4, is described in detail with reference to the flowchart of Figure 6. Within each 2 second display cycle, the CFM indicator level is determined by converting the value of AVE4 to percent and comparing it to the following limits:

```
LEVEL 1:  4.5% TO 15%
LEVEL 2:  4.0% TO 4.5%    OR    15% TO 18%
LEVEL 3:  3.5% TO 4.0%    OR    18% TO 22%
LEVEL 4:  LESS THAN 3.5% OR GREATER THAN 22%
```

Thus if the value of AVE4*100 = 12, then the CFM indicator will be set to a value of 1.

Clipping Frequency Indicator:

The CFI value is determined as a function of the number of clipped values (NC) in the last 500 ms update cycle as well as the last CFI value. At each CFM level, local variables Z, UP, and DN are assigned set values. Another local variable W is then calculated as a function of the last W value, NC and Z. The CFI level is then adjusted as a function of the value of W. In a preferred embodiment, the CFI level is determined according to the following procedure:

Initially, the local variables Z, UP, and DN are set, as a function of the last CFI level.

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```
   IF CFI = 1,  THEN   Z=6, UP=49, and DN=0;
   IF CFI = 2,  THEN   Z=10, UP=104, and DN=11;
   IF CFI = 3,  THEN   Z=14, UP=164, and DN=51;
5  IF CFI = 4,  THEN   Z=18, UP=175, and DN=101;
```

The value of the variable W is then calculated as:

$$W = W_p + 4*NC - Z \qquad (13)$$

10

Where W_p is the value of W for the preceding 500 ms time period. Thus, the calculation of the value W is recursive in that the prior value of W is used as an input value for calculating the current value of W. If the calculated value of W is less than zero, then W is assigned a value of zero. If the calculated value of W exceeds 175, then W is assigned a value of 175. This is done to insure that W does not fall outside of the acceptable range. If the value of W is greater than the current value of UP, then this indicates that the blood oxygenation saturation level reading has become less reliable, and the CFI value is incremented by one. However, if the value of W is less than the current value of DN, this indicates that the blood oxygenation saturation level reading has become more reliable, and the CFI level is decremented by one. If the value of W falls between the current values of UP and DN, then the CFI value remains the same. In this manner the CFI level may be determined.

Once the indicator levels have been determined for the IS, CFM and CFI conditions, the final quality display signal is determined as the highest of the three, and output as a bar graph display 120 on the display panel of the monitoring system 100. Thus, a method and apparatus are provided for the monitoring of the reliability of the blood oxygenation saturation level reading.

The invention may be embodied in other specific forms

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without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects as illustrative and not restrictive. The scope of the invention is, therefore,
5 indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

WHAT IS CLAIMED IS:

1. A cardiopulmonary monitoring apparatus for connection to a catheter having fiber optics which transmit optical signals to and from the interior of a blood vessel, said monitoring apparatus comprising:

a detector for detecting an optical signal transmitted from said blood vessel and generating an output signal in response thereto; and

a signal processing device comprising first signal processing means for (i) comparing the amplitude of said output signal with a threshold amplitude value, (ii) monitoring the frequency with which said output signal exceeds the threshold value during a selected interval of time and (iii) generating a first indicator based on said frequency.

2. The apparatus of Claim 1, wherein the value of said first indicator for said selected interval of time is based on the value of the first indicator during a preceding interval of time.

3. The apparatus of Claim 1, wherein the first indicator for said selected time interval is dependent on a variable W, said variable W being a function of (i) the variable W for a preceding interval of time, (ii) the frequency with which the output signal exceeds the threshold value during the selected time interval, and (iii) a variable Z which is function of the value of the first indicator during the preceding interval of time.

4. The apparatus of Claim 3, wherein the value of the first indicator for the selected time interval remains equal to the value of the first indicator for the preceding time interval unless the variable W is outside of a predetermined range, said predetermined range being a function of the value of the first indicator S for the preceding time interval.

5.   The apparatus of Claim 1, wherein said signal processing device additionally comprises second signal processing means for generating a second indicator signal.

6.   The apparatus of Claim 5, wherein said signal processing device additionally comprises third signal processing means for generating a third indicator.

7.   The apparatus of Claim 6, additionally comprising means for sensing said first, second, and third indicators and responsively generating a display signal.

8.   The apparatus of Claim 7, wherein said display signal has a value corresponding to the highest of said first, second, or third indicators.

9.   The apparatus of Claim 5, wherein said second signal processing means monitors the magnitude of variations in said output signal caused by pulsatile blood flow through said blood vessel.

10.   The apparatus of Claim 6, wherein said third signal processing means monitors the amplitude of said output signal.

11.   A cardiopulmonary monitoring apparatus for connection to a catheter having fiber optics which transmit optical signals to and from the interior of a blood vessel, said monitoring apparatus comprising:

a detector for detecting an optical signal transmitted from said blood vessel and generating an output signal in response thereto, said output signal having a waveform;

means for recursively generating a variable indicative of a characteristic of said waveform; and

means for generating an indicator based on said variable.

12.   The apparatus of claim 11, wherein said waveform characteristic comprises spikes in said waveform.

13.   A method of monitoring an optical signal from a cardiopulmonary catheter, comprising:

detecting said optical signal and generating a

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waveform in response thereto;

    monitoring spikes in said waveform during a first time interval;

    monitoring spikes in said waveform during a second interval; and

    utilizing the results of steps (b) and (c) to generate an indicator.

14. The method of Claim 13, additionally comprising the step of comparing the indicator with another indicator and generating a display signal based on the results of the comparison.

15. The method of Claim 14, wherein the display signal has a value corresponding to the value of the highest of said indicators.

Fig. 1

Fig. 2

Fig. 3

Fig. 4

Fig. 5

BEGIN — 500

INITIALIZATION AND SELF TEST — 510

DATA ACQUISITION AND FILTERING — 520

CALIBRATION AND UPDATE — 530

CALCULATE AND DISPLAY BLOOD SATURATION LEVEL — 540

CHECK FOR ALARM CONDITIONS — 550

ALARM ? — 555

YES

NO

UPDATE QUALITY DISPLAY SIGNAL — 570

DISPLAY ALARM — 560

Fig. 6A

```
                          ( BEGIN )  600
                               |
                               |          602
                               v
                         /  GATE      \                    MULTIPLY DATA   610
                YES     / ARRAY IN OFFSET \     NO          BY MAXIMUM
            <----------<    MODE ?         >---------->        GAIN
            |           \                /                        |
            |            \              /                         |
            |              \          /                           v
            |                                               SET INITIAL
            v                                                THRESHOLD
      CALCULATE                                               VALUES      612
      OFFSETS FOR   604                                           |
      EACH GAIN                                                   v
      LEVEL                                               CALCULATE
            |                               614           LIMRNEW AND
            |                                              LIMINEW
            v                                                   |
      STORE OFFSET   606                                        v
      VALUES INTO                           616          CALCULATE
      RAM                                                MINIMUM
            |                                            LIMIT LIMMIN
            |                              611                   |
            |                                                    |   618
            |                                                    v
                                                         /  LIMMIN >  \
   NEW THRESHOLD                          NO            / LIMRNEW       \
   VALUES FOR R AND   628      822    <---------------<       ?         >
   IR SIGNALS                    \     /  LIMMIN >  \          \       /
   CALCULATED AS:          626    \   / LIMINEW      \  YES     \     / YES
   LIMRED =                  \     X <      ?          >         v
   INT[(3*LIMRED+LIMRNEW)]  NO \  / \      /          /    LIMRNEW=LIMMIN
              4           <------X NC=2D OR \        /           |
   LIMIR =                     / NC=0        \      / YES      620
   INT[(3*LIMIR+LIMINEW)]      \    ?        /     v
              4                 \          /   LIMINEW = LIMMIN   624
            |                      YES
            |                       |
            |                       v
            |              LIMRED=LIMRNEW   630                  FILTER AND   650
            |              LIMIR = LIMINEW                       AVERAGE
            |<---------------------                             SIGNAL TO
            |                                                   OBTAIN F2
            v                                                   AND
   634     638      642              644                        AVE2
   / RED> \  NO   E2RED=   / IRED> \  NO   E2IR =                  |
  < LIMRED >---->  RED    < LIMIR   >----> IRED                   |
   \  ?   /         |      \   ?   /        |                     |
    \    / YES      |       \    / YES      |                     |
  636  |           |    646  |             |                     |
       v           |         v             |                     |
   E2RED=LIMRED    |    E2IR = LIMIR        |                    ( A )
   NC = NC+1 ------+    NC = NC+1 ----------+
```
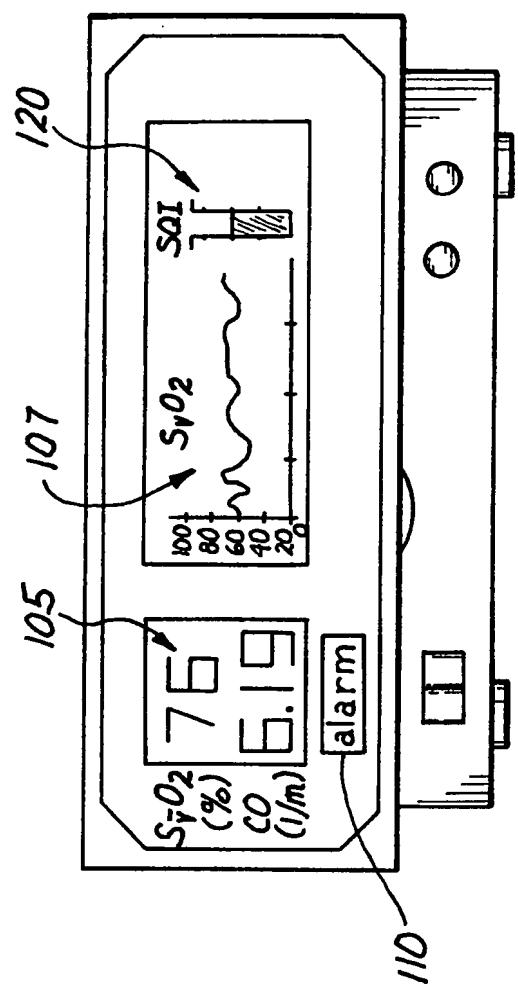
A

CALCULATE OUTPUT
VALUES FOR R AND IR
AS: REDOUT = AVE 2R -
OSRED
IROUT = AVE 2IR - OSIR

654

STORE VALUES OF
REDOUT AND IROUT
IN RAM

658

CALCULATE
DIFFERENCE
SIGNAL AS:
E3IR = |E2IR - F2IR|

662

FILTER AND AVERAGE
E3IR TO OBTAIN
F3IR AND AVE3IR

668

$$E4 = \frac{AVE\,3IR}{IROUT}$$

672

FILTER AND AVERAGE
E4 TO OBTAIN
F4 AND AVE4

676

Fig. 6B

CFM = AVE4

680

END

700 BEGIN

710 DETERMINE IS
SIGNAL QUALITY
INDICATOR

720 DETERMINE
CFM SIGNAL
QUALITY
INDICATOR

730 DETERMINE
CFI SIGNAL
QUALITY
INDICATOR

740 SELECT HIGHEST
FROM IS, CFI,
AND CFM AS
DISPLAY SIGNAL
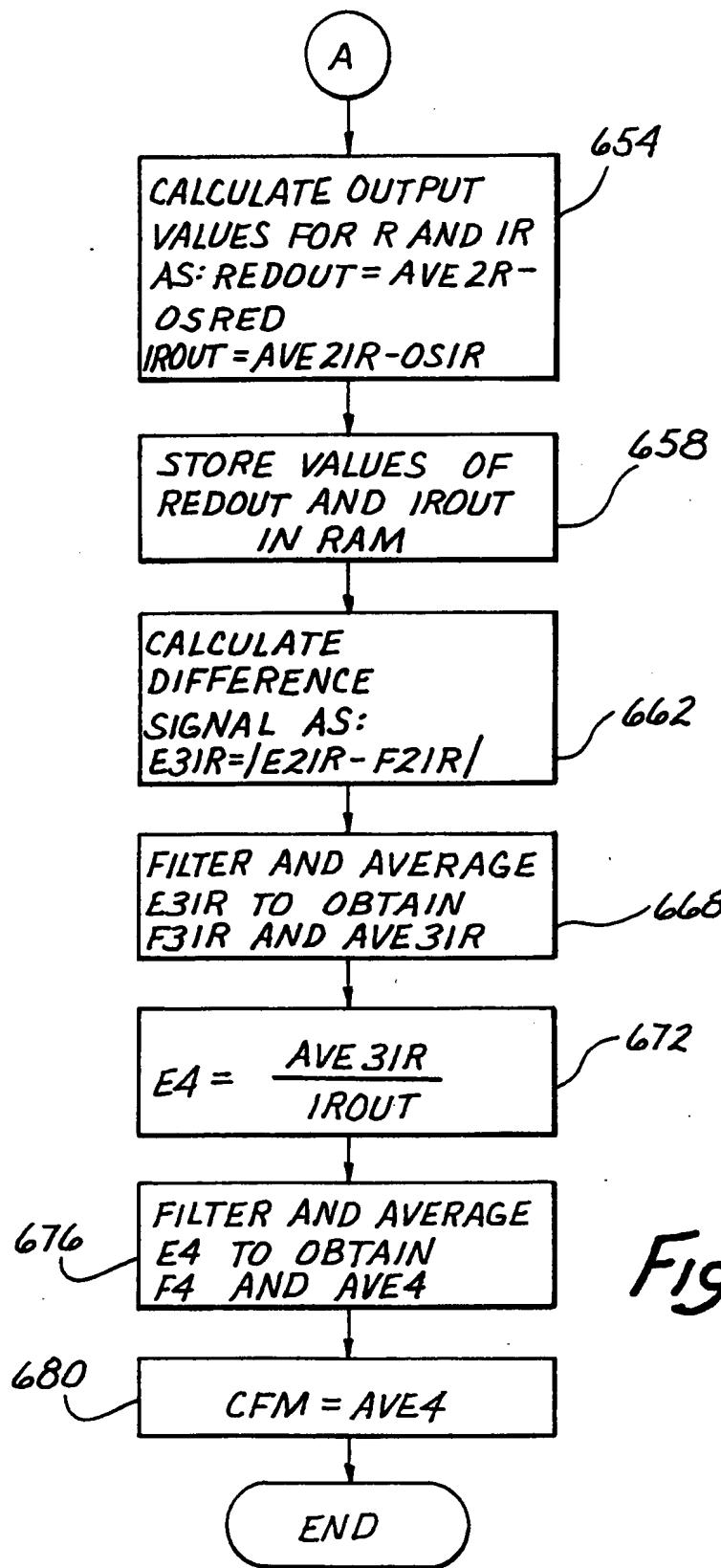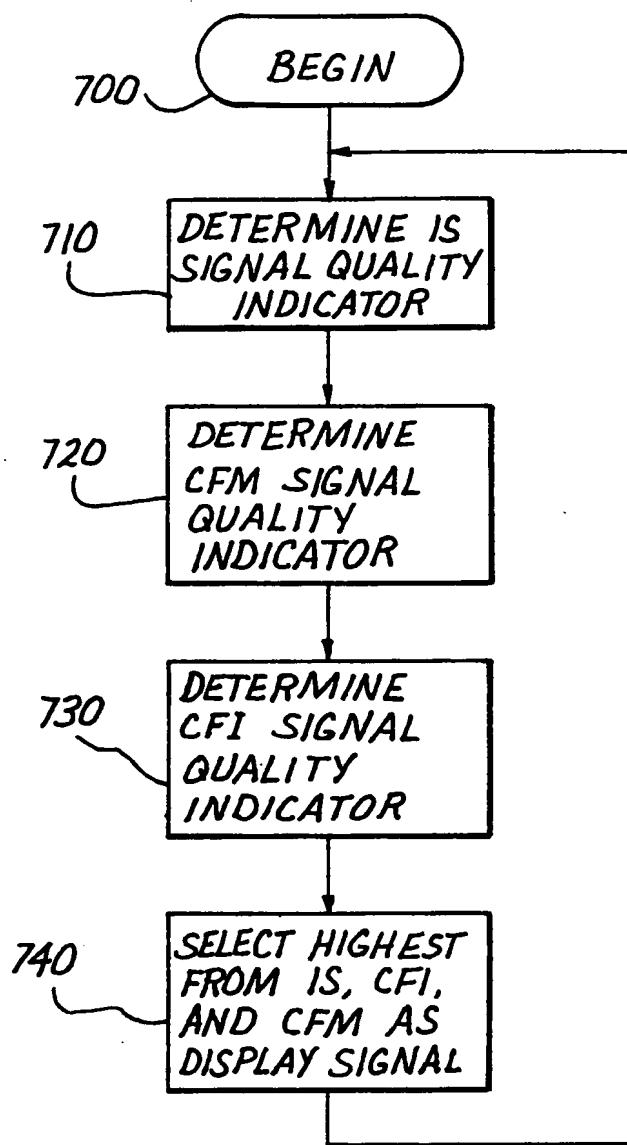
Fig. 7

INTERNATIONAL SEARCH REPORT

PCT/US 92/00298

International Application No

I. CLASSIFICATION OF SUBJECT MATTER   (if several classification symbols apply, indicate all)⁶

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl. 5 A61B5/00;   G06F15/20

II. FIELDS SEARCHED

Minimum Documentation Searched⁷

Classification System	Classification Symbols
Int.Cl. 5	A61B ; G06F

Documentation Searched other than Minimum Documentation
to the Extent that such Documents are Included in the Fields Searched⁸

III. DOCUMENTS CONSIDERED TO BE RELEVANT⁹

Category°	Citation of Document,¹¹ with indication, where appropriate, of the relevant passages¹²	Relevant to Claim No.¹³
Y	WO,A,8 201 948 (OXIMETRIC INC.) 10 June 1982	1,2,11, 12,13
A	see abstract see page 1, line 27 - page 3, line 29 see page 5, line 12 - line 29 see page 8, line 18 - page 12, line 17; figures 1-3 ---	3,4
Y	WO,A,9 009 144 (PRECOR INCORPORATED) 23 August 1990	1,2,11, 12,13
A	see page 12, line 35 - page 13, line 38 see page 15, line 15 - page 16, line 8 see page 24, line 3 - page 26, line 11; figures 1-3,5,6 ---	9,10
A	EP,A,0 245 039 (WESTINGHOUSE ELECTRIC CORPORATION) 11 November 1987 see page 8, line 11 - line 24 ---	5-8,14, 15

° Special categories of cited documents :¹⁰

"A" document defining the general state of the art which is not considered to be of particular relevance

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"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
24 APRIL 1992	15. 05. 92

International Searching Authority	Signature of Authorized Officer
EUROPEAN PATENT OFFICE	FONTENAY P.H.

Form PCT/ISA/210 (second sheet) (January 1985)

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report.
The members are as contained in the European Patent Office EDP file on
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For more details about this annex : see Official Journal of the European Patent Office, No. 12/82